METHOD AND APPARATUS FOR CHEST DRAINAGE

Priority Claim

[0001] This application is a continuation of U.S. application Serial No. 09/908,316, filed on July 17, 2001, now U.S. Pat. No. 6,638,253.

Field of the Invention

[0002] The field of this invention is general surgery, thoracic surgery, trauma and critical care.

Background of the Invention

[0003] Chest drainage tubes are used following thoracic surgery, chest trauma or to treat certain medical conditions. The purpose of a chest tube is to remove buildup of excessive body fluids, contaminants or air from the thoracic cavity. The presence of an opening into the chest or thorax, created with or without a cannula will cause pneumothorax (collapsed lung). Negative pressure in the chest cavity is created by the chest muscles and diaphragm in order to cause lung expansion and resulting inspiration of a breath. Therefore, a hole in the chest will equalize pressure and prevent critical lung function, i.e. lung insufflation. Any cannula placed into a patient's chest cavity for drainage must be sealed to prevent pneumothorax from occurring.

[0004] Current chest drainage cannulae, also called chest tubes, drainage catheters or drainage cannulae, are flexible polymer tubes, placed into the chest cavity and extending outside the patient.

[0005] Chest drainage tubes are placed using a surgically invasive procedure. Generally, if a surgical incision into the chest has not been made, the chest tube is usually placed with the aid of an internal trocar that stiffens the chest tube and allows for easier chest wall penetration during placement. The procedure begins with a skin incision large enough to accommodate the diameter of the selected chest tube. Chest tubes are typically 8mm to 10mm diameter. The internal trocar, having a sharp point, is placed inside the chest tube. The pointed end of the trocar chest tube combination is pressed through the skin incision and plunged into the thoracic cavity through the muscle, fascia and fat layers of the patient, through the rib space and into the pleural cavity. The trocar is removed and the chest tube is clamped to prevent pneumothorax.

[0006] When drainage is required, the clamp is opened and fluid, air and contaminants are removed from the thoracic cavity. The fluid, air and contaminants typically are removed, forcefully, by use of external vacuum or pumping systems. The clamp is closed once drainage is completed to avoid reflux of fluid and air back into the chest cavity and possible generation of pneumothorax or influx of contaminants (i.e. infectious agents).

[0007] Placement of current chest drainage tubes is an invasive surgical procedure. With any invasive surgical procedure, there exists a risk of iatrogenic trauma to the patient. Significant training is required to safely perform these procedures and this training may not have been completed by emergency personnel who are the first line of treatment for many patients experiencing trauma.

[0008] Improved valving mechanisms would increase functionality of chest drainage tubes and overcome issues that occur with clamp application and removal. There are also fewer steps required of the medical practitioner in chest drainage when a tube with an internal valving mechanism is employed. There may also be a problem with a chest tube being pushed too far into the patient, resulting in kinking, compromised drainage and potential iatrogenic damage to internal organs.

Summary of the Invention

[0009] This invention relates to a catheter, tube or cannula for draining fluid, air and contaminants from the chest and a method of placement.

[0010] The cannula of the present invention includes an internal, semi-automatic valving mechanism, which allows for fewer steps and minimizes the chance of leaving the chest tube open to atmosphere when drainage is completed. The cannula of the present invention also comprises an external movable fixation device to prevent inadvertently pushing the cannula too far into the patient. The minimally invasive placement method of the present invention is beneficial in not only the emergency setting but also in the hospital setting by reducing the chance of iatrogenic injury to the patient.

[0011] The cannula is a polymeric tube, preferably with a metal spiral winding to prevent kinking or collapse, which is fenestrated at or near the distal tip at a plurality of sites. The cannula includes an interior valve or seal, located

inside the drainage lumen of the cannula, operably able to prevent reflux or efflux of fluid, air and contaminants to or from the chest. The cannula includes an intracorporeal fixation device, located internal to the patient, to prevent outward dislodgement of the chest tube from the chest. The cannula also includes an extracorporeal fixation device, located external to the patient to prevent inward movement of the chest tube.

[0012] In one embodiment, application of a vacuum at the proximal end of the cannula causes the internal valve to open thus allowing free flow of fluid, air and contaminants from the chest through the cannula and into the drainage system. The drainage system is typically a vacuum powered, water sealed suction device and collection reservoir. Removal of the vacuum causes exposure of the valve to atmospheric pressure and subsequent closure of the valve, thus reflux of fluid, air and contaminants into the chest is prevented.

[0013] Alternatively, the valve could be operated by application of positive pressure (above atmospheric) for closure of the valve and application of negative or zero pressure to open the valve. External feedback systems utilizing pressure sensors or other devices are used to ensure patient safety with the positive pressure valve closure embodiment.

[0014] In another embodiment, the internal valve is placed at the proximal end of the cannula. This valve is fabricated from a soft polymeric compound or foam with a central hole that is normally closed. Application of a mechanical force through the center of the valve, with a hollow obturator, for example, opens

the valve and allows flow through the hollow obturator. Removal of the hollow obturator causes closure of the valve and prevention of reflux back into the thoracic cavity.

[0015] In yet another embodiment, the valve is a duckbill valve that passively prevents reflux back into the thoracic cavity while allowing drainage from the chest cavity under application of appropriate pressure drop across the valve. Such pressure drop can occur from an increase of intrapleural pressure caused by buildup of fluids or by application of a vacuum to the outlet side of the valve.

[0016] In all embodiments, the valve systems are, preferably, integral to the cannula and unable to be separated from the cannula when, for example, the patient rolls over and stresses the connection.

[0017] The drainage cannula of the present invention includes an intracorporeal fixation or retaining device that prevents the cannula from being removed inadvertently from the patient. This intracorporeal device is, for example, an elastomeric or inelastic (i.e. angioplasty-type) balloon affixed to the exterior surface of the cannula. The balloon is passed inside the chest cavity and is inflated with sterile liquids or air to prevent withdrawal through the hole or wound in the chest wall. Inflation typically occurs using a balloon inflation lumen in the cannula, inflation ports between the lumen and the balloon, and an inflation device external to the cannula.

[0018] Additionally, the drainage cannula of the present invention includes an extracorporeal fixation device that may comprise one or more clips that are affixed to the exterior of the cannula in a movable fashion. These clips are, preferably, located proximally to the internal fixation device or balloon. They may be moved against the chest wall and frictionally engaged to the cannula shaft to prevent the cannula from being forced too far into the patient. Such extracorporeal fixation devices could be retrofitted to existing chest tubes to improve the functionality of existing chest tubes.

[0019] The chest drainage tube of the current invention is placed in a minimally invasive procedure. Placement is accomplished by first performing a surgical skin nick and then placing a hypodermic needle into the pleural space of the patient at the site of the skin nick. A J-tip guidewire is placed through the hypodermic needle and the hypodermic needle is removed. A percutaneous access device or trocar is placed into the central lumen of the chest tube and over the guidewire and routed into the pleural space.

[0020] In a further embodiment, the cannula is steerable. This is accomplished by use of a malleable, bendable trocar that can be shaped prior to insertion into the patient. In another embodiment, steerability is obtainable by heat setting the cannula with a curved shape. Axially moving a rigid straight trocar into the bent portion of the cannula from the proximal end causes the curved shape to straighten out. This controllable bending is useful for negotiating tight turns in the patient. In another embodiment, steerability may be obtained

using actuators on the surface or within the interior of the cannula to force bending of the cannula. These actuators are typically electrically powered. An actuator comprises electrical leads, a power source, a compressible substrate, and shape memory materials such as nitinol. Such actuators may be distributed along the length of the cannula. The actuators may be placed so as to oppose each other. Opposing actuators are activated one at a time and not simultaneously.

[0021] The combination of minimally invasive placement and reduced steps to operate the chest drainage tube will benefit patients and medical practitioners by reducing errors, minimizing trauma, increasing ease of use, and improving patient outcomes.

Brief Description of the Drawings

[0022] Figure 1 illustrates the cannula, according to aspects of an embodiment of the invention;

[0023] Figure 2 illustrates a cross-section of multi-lumen tubing used in fabrication of the cannula, according to aspects of an embodiment of the invention;

[0024] Figure 3A illustrates a trocar useful for surgical placement of the cannula, according to aspects of an embodiment of the invention;

[0025] Figure 3B illustrates the cannula with the trocar of Figure 3A inserted therein, according to aspects of an embodiment of the invention;

[0026] Figure 4A illustrates the percutaneous access trocar, guidewire and hollow needle for the method, according to aspects of an embodiment of the invention;

[0027] Figure 4B illustrates the cannula with the percutaneous access trocar of Figure 4A inserted therein, according to aspects of an embodiment of the invention;

[0028] Figure 5A illustrates the cannula with the selectively openable, slotted distal drainage apparatus, wherein the slots are closed, according to aspects of an embodiment of the invention;

[0029] Figure 5B illustrates the cannula with the selectively openable, slotted distal drainage apparatus, wherein the slots are opened, according to aspects of an embodiment of the invention; and

[0030] Figure 5C illustrates a vertical cross section of the proximal end of the cannula, according to aspects of an embodiment of the invention.

Detailed Description of the Invention

[0031] Figure 1 illustrates a cannula, tube or catheter **10** of the present invention. The catheter **10** comprises a manifold or hub **12**, a valve or seal **14**, an extracorporeal fixation device **16**, an intracorporeal fixation device **18**, a plurality of drainage holes **20**, and a length of multi-lumen tubing **22**. In addition, the catheter **10** optionally comprises a valve housing **15**. The manifold **12** comprises a drainage adapter or fitting **24**, a valve-enabling adapter or fitting **26**, and an intracorporeal fixation-enabling adapter or fitting **28**. In this preferred

embodiment, the intracorporeal fixation device **18** is a balloon, and the intracorporeal fixation-enabling adapter **28** is a balloon inflation adapter or fitting. The multi-lumen tubing preferably comprises a stiffening wire **30**.

[0032] Figure 2 illustrates a cross-section of the multi-lumen tubing **22**. The multi-lumen tubing **22** comprises a drainage lumen **32**, a valve enabling lumen **34**, an intracorporeal fixation-enabling lumen **36**, and a wall **38**. In this preferred embodiment, the intracorporeal fixation-enabling lumen **36** is an inflation lumen. There is no communication between the drainage lumen **32**, the inflation lumen **36** and the valve enabling lumen **34**. The tubing material may be selected from any polymer such as, but not limited to, polyvinyl chloride, polyurethane, polyethylene and the like. The tubing **22** is, preferably, transparent or semi-transparent. At least a portion of the tubing **22** is preferably stiffened with a helical winding of material such as stainless steel, nitinol and the like. The stiffening **30** could also be created using corrugations in the tubing **22** or by addition of a strong polymer such as glass-filled polycarbonate instead of the metal helical winding. The stiffening member **30** serves the purpose of preventing collapse of the cannula **10** when vacuum is applied to the drainage lumen **32**. The stiffening member **30** also serves to prevent kinking when the cannula **10** is bent around a tight radius.

[0033] Referring to Figures 1 and 2, the manifold **12** connects to the proximal end of the length of multi-lumen tubing **22** such that the drainage adapter **24** connects to the drainage lumen **32**, the balloon inflation adapter **28**

connects to the inflation lumen **36**, and the valve-enabling adapter **26** connects to the valve-enabling lumen **34**. There is no communication between the drainage adapter **24**, the balloon inflation adapter **28**, and the valve–enabling adapter **26**. The manifold **12** is typically molded from polymer, such as polyvinyl chloride, polycarbonate, acrilonitrile butadiene styrene (ABS), or the like.

[0034] The distal end of the multi-lumen tubing **22** comprises the plurality of drainage holes **20**. The drainage holes **20** connect the exterior of the catheter **10** with the drainage lumen **32**. The holes **20** are of sufficient size and quantity to allow for passage of fluid, thrombus and debris that might need to be removed from the chest cavity. The plurality of drainage holes **20** and the drainage lumen **32** may further be coated with an anti-thrombogenic coating of material such as, but not limited to, heparin.

[0035] The valve or seal **14** is preferably located in the drainage lumen **32** of the catheter **10**, between the manifold **12** and the drainage holes **20**. Alternatively, the valve or seal **14** may be mounted proximal to the manifold **12** or inside the manifold **12**. If the optional valve housing **15** is used, the housing **15** encircles the catheter **10** and is open to the drainage lumen **32**. The valve **14** sets inside the housing **15**. The intracorporeal fixation balloon **18** is located on the outside surface of the multi-lumen tubing **22**, between the manifold **12** and the drainage holes **20**, approximately 2 cm to 40 cm from the most proximal drainage hole. More preferably, the intracorporeal fixation device or balloon **18** is located between 5 cm and 20 cm from the most distal drainage hole. The

balloon **18** is located over a balloon inflation port that allows communication between the balloon **18** and the inflation lumen **36**. The extracorporeal fixation device **16** is slidably located on the outside of the multi-lumen tubing **22**, between the manifold **12** and the intracorporeal fixation balloon **18**.

[0036] When the catheter **10** is in use, the manifold **12** connects to a drainage system through the drainage adapter **24**. The drainage adapter **24** is typically larger in diameter than the balloon inflation fitting **28** or valve-enabling fitting **26**. The drainage adapter **24** is capable of being connected to the gravity-fed, pump-driven or vacuum-fed drainage system and is most typically a 3/8 inch to ½ inch diameter hose barb. Standard drainage systems generally comprise a connector, a length of tubing and a reservoir. Optionally, a vacuum pump may be connected to the reservoir.

[0037] The manifold **12** also connects to an inflation system through the balloon inflation adapter **28**. The balloon inflation adapter **28** is typically a female luer fitting but may be any fluid-tight fitting suitable for use with an inflation syringe or the like. The standard balloon inflation system comprises a syringe, a volume of balloon inflation fluid such as sterile saline, air or radiopaque media, and a valve or stopcock. Additionally, the balloon inflation system could comprise a device, such as a jackscrew, to advance or withdraw a plunger on the syringe using mechanical advantage.

[0038] Additionally, the manifold **12** connects to a valve enabling system through the valve-enabling adapter **26**. The valve-enabling adapter **26** is,

preferably, a female luer lock adapter, but could be another type of fluid-tight connection such as a threaded swage-lock, or the like.

[0039] Figure 3A illustrates a trocar **40** useful for surgical placement of the cannula **10** of the present invention. The trocar **40** comprises a plunger **42**, a body **44** and a pointed tip or needle **46**. Figure 3B shows the trocar **40** inserted into the drainage lumen **32** of the catheter **10**. The needle **46** extends out from the distal tip of the catheter **10** and the plunger **42** extends out from the proximal end of the catheter **10**. The internal trocar **40** stiffens the chest tube **10** and allows for easier thoracic penetration during placement. The internal trocar **40** is typically made from metal or polymer. The internal trocar **40** is, optionally, fabricated to be malleable. Medical personnel make a skin incision large enough to accommodate the diameter of the chest tube **10**. Chest tubes **10** are typically 8mm to 10mm diameter. The pointed needle **46** of the trocar chest tube combination **40,10** is pressed against the skin incision. Medical personnel push the plunger **42** to force the needle **46** into the thoracic cavity through the muscle, fascia and fat layers of the patient, through the rib space and into the pleural cavity. The trocar **40** is removed and the chest drainage tube **10** is in place. Fixation devices are enabled at this point.

[0040] Figures 4A and 4B illustrate a more preferred method of chest drainage tube placement. Figure 4A illustrates a kit **48** comprising a hollow needle **50**, a guidewire **52**, and a tapered, flexible trocar **54**. The trocar **54** comprises a tip **56** and a handle **58**. First, the hollow needle **50** is inserted into

the chest between the ribs, through the skin, fat, intercostal muscle, fascia and pleura. Next, the guidewire **52** is inserted through the needle **50** into the chest cavity to the desired location of the distal tip of the cannula **10** or beyond. Preferably, the guidewire **52** has a J-tip configuration at its distal end.

[0041] As shown in Figure 4B, the tapered, flexible trocar **54** is inserted into the cannula **10** such that the tip **56** of the trocar **54** extends through the distal tip of the cannula **10** and the handle **58** of the trocar **54** extends through the proximal end of the cannula **10**. The needle **50** is removed and the flexible trocar-cannula combination **54,10** is threaded over the proximal end of the guidewire **52**. The flexible trocar-cannula combination **54,10** is moved over the guidewire **52** and inserted through the hole in the chest formed by the needle **50**. The tapered trocar **54** expands the chest hole and allows passage of the larger diameter back section of trocar **54** and cannula **10** into the patient. The trocar **54** and cannula **10** are advanced to the desired intrathoracic site along the route described by the guidewire. Once the tip **56** of the trocar **54** is in the desired location, the trocar **54** is removed from the proximal end of the cannula **10**. This method of cannula placement using the flexible, tapered trocar **54** requires a smaller incision than a standard trocar **40**. The incision may even be a percutaneous stick. The additional benefit is that the flexible trocar **54** and cannula **10** follow the path created by the guidewire **52** and route to the desired location without damaging tissue inadvertently. The tapered, flexible trocar **54** is typically fabricated from polymers such as PVC or polyethylene. The tapered,

flexible trocar **54** exhibits column strength but is bendable. The tapered, flexible trocar **54** is able to flex easily along the path described by the guidewire **52**.

[0042] Referring to Figures 1 and 2, once the chest drainage tube **10** is placed in the patient's chest, the intracorporeal fixation balloon **18** is inflated. Balloon inflation fluid from the balloon inflation system is injected into the balloon inflation lumen **36** through the balloon inflation fitting **28**. The balloon inflation fluid travels through the balloon inflation lumen **36** to the balloon inflation port. The balloon inflation fluid travels through the balloon inflation port into the balloon **18**, inflating the intracorporeal fixation balloon **18**. The valve or stopcock on the balloon inflation system is closed to maintain the balloon **18** in the inflated configuration. The stopcock remains attached to the balloon inflation adapter to prevent unwanted balloon deflation. The balloon **18** is inside the patient's chest and is larger than the chest incision. The balloon **18** prevents the chest drainage tube **10** from inadvertently being pulled out of the patient. The balloon inflation fluid is selectively drained from the intracorporeal fixation balloon **18** by opening the stopcock to deflate the balloon **18** and allow the cannula **10** to be removed from the patient's chest.

[0043] In another embodiment, the intracorporeal fixation device **18** is an expandable region of cylindrical material with longitudinal slits or slots, a distal ring and a proximal ring. The rings and interconnecting slotted cylinder are disposed coaxially and concentrically around the cannula **10** shaft. The distal ring is connected to a control rod routed through the intracorporeal fixation lumen

36 to a control handle on the proximal end of the cannula **10**. When the cannula **10** is in place, the control rod is pulled, causing the distal ring of the intracorporeal fixation device **18** to pull along the cannula **10** shaft, toward the proximal ring. This causes the slit cylinder to collapse in length and the cylinder material between slits expands in diameter, forming a starburst pattern. A locking mechanism at the proximal end of the cannula **10** keeps the control rod from moving once the intracorporeal fixation device **18** is opened in the desired position. This system functions like a moly-bolt or drywall anchor to keep the cannula **10** from being removed from the chest inadvertently. The control rod may be unlocked and the distal ring advanced distally to contract the anchor around the cannula **10** so the cannula **10** may be removed from the patient. Optionally, holes or openings in the cannula **10** that connect with the drainage lumen **32** may be disposed underneath the slots or slits of the intracorporeal fixation device **18** thus providing additional chest drainage ports when the intracorporeal fixation device **18** is in the open position.

[0044] In addition to enabling the intracorporeal fixation device **18**, the extracorporeal fixation device **16** is also enabled once the catheter **10** is in place in the patient's chest. The extracorporeal fixation device **16** is located outside the chest and is disabled to allow the fixation device **16** to slide over the exterior of the catheter **10**, into place, against or close to the patient's skin. The extracorporeal fixation device **16** is enabled and forcibly stops sliding, preventing the chest drainage tube **10** from inadvertently being pushed farther into the patient's chest.

[0045] In a preferred embodiment, the extracorporeal fixation device **16** is a lockable clip device. When the lock is open, the extracorporeal fixation device **16** slides over the catheter **10**. When the desired location on the catheter **10** is reached, the lock is closed and the extracorporeal fixation device **16** engages the catheter **10** with enough force to make dislodgement of the fixation device **16** relative to the cannula or catheter **10** difficult, but with insufficient force to crimp or restrict the catheter **10** or the lumens **32,34,36**. The clip **16** is considerably larger than the diameter of the catheter **10** and the incision in the chest and, preferably has atraumatic rounded edges where it contacts the patient. At least one lateral dimension of the external fixation device or clip **16** is generally between 0.25 and 2 inches. More preferably, the external fixation device or clip **16** is between 0.5 and 1.0 inches in lateral dimension.

[0046] In another embodiment, the extracorporeal fixation device **16** is an inflatable balloon. The extracorporeal fixation balloon **16** may be inflated from the balloon inflation lumen **36** used to inflate the intracorporeal inflation balloon **18**. Alternatively, the extracorporeal inflation balloon **16** may be inflated from an additional balloon inflation lumen.

[0047] In yet another embodiment, the extracorporeal fixation device **16** is an opposably engaged spring clip, which encircles the catheter **10**. When the spring is compressed, the clip **16** is slid to the desired location on the catheter **10**. When the pressure on the spring is released, the clip **16** is locked into place on the catheter **10**. A similar type of spring clip is used to secure a drawstring on

a sleeping bag. A further embodiment of the extracorporeal fixation device **16** is a rocking clip that slides when it is tilted relative to the lateral axis of the cannula **10** and locks when it is in the plane perpendicular to the axis of the cannula **10**.

[0048] In another embodiment, the extracorporeal fixation device **16** comprises a penetrable polymeric tab to allow suture passage and attachment of the extracorporeal fixation device **16** to the patient's skin with suture. The distal side of the extracorporeal fixation device **16** may comprise an adhesive layer to facilitate not only fixation but provide a contamination barrier at the entry site. The extracorporeal fixation device **16** optionally comprises a hole located somewhere on its structure, through which suture may be passed to facilitate attachment to the patient's skin.

[0049] In yet another embodiment, the extracorporeal fixation device **16** slides over a plurality of bumps or detents on the cannula **10** exterior surface. These bumps or detents serve to prevent axial motion of the extracorporeal fixation device except under substantial selective manual force. The extracorporeal fixation device **16** may additionally have a ratcheting mechanism that allows for axial motion toward the patient but prevents motion in the reverse direction away from the patient.

[0050] The extracorporeal fixation device is useful to retain not only drainage tubes but also any type of catheter in place in the patient.

[0051] Once the catheter **10** is placed in the patient's chest, the valve **14**, which is normally closed, prevents pneumothorax from occurring. The normally closed valve **14** seals the drainage lumen **32**. When the medical personnel require chest drainage, the valve **14** is enabled or opened to allow fluid, air and contaminants to drain from the chest drainage tube **10**.

[0052] In one embodiment, the valve-enabling lumen **34** is connected through the valve-enabling adapter **26** to a vacuum system. The typical vacuum system is operated by an electrical vacuum pump and regulator to maintain a low level vacuum of 1 to 100mm Hg. Preferably, the vacuum is maintained at a level of 1 to 20mm Hg. When the vacuum system is activated, a vacuum is drawn through the valve-enabling lumen **34** and the valve **14** opens. Stopping the vacuum system causes the valve **14** to close and seal the drainage lumen **32**.

[0053] The preferred vacuum activated valve embodiment **14** is one or more balloons mounted within the drainage lumen **32** of the cannula **10**. More preferably, the balloons **14** are exposed to the drainage lumen **32** but reside within the optional valve housing **15** that is larger than the diameter of the drainage lumen **32**. The collapsed balloons **14** reside within the housing **15** and do not impinge on the drainage lumen **32** where they could impede passage of the trocar **40** or **54**. The balloons **14** are maintained in their collapsed state and out of the drainage lumen **32** by application of a vacuum through the valve-enabling adapter **26** and the valve-enabling lumen **34**. An optional stopcock on the valve-enabling adapter **26** is closed to maintain the vacuum until it is desired

to close the drainage lumen seal **14**. The valve housing **15** is fabricated, preferably, from transparent materials in order to allow for visualization of valve function and verification of drainage lumen patency. The balloons **14** are made with open cell foam. Such open cell foams are typically made from polyurethane materials and the spaces between the cells in the foam interconnect. The skin or surface of the balloon **14** is a fluid impermeable, elastomeric material such as latex, polyurethane, silastic, silicone elastomer and the like.

[0054] The balloons **14** are inflated, thus closing the valve **14**, by resilient expansion of the foam after fluid is allowed to flow back into the collapsed balloons. This may be done by removal of the vacuum or by opening the stopcock. When the valve **14** is closed, drainage through the drainage lumen **32** stops and the chest opening is sealed. The valve **14** is opened by application of a vacuum to the valve enabling lumen **34**. The vacuum system can be operably connected to the same vacuum system used for drainage of the thorax. In this way, the valve **14** automatically opens when drainage is activated.

[0055] Other valve embodiments **14** include balloons that are normally deflated and open. These valves **14** require that positive pressure be applied to inflate the balloons and occlude the drainage lumen **32**. Removal of the pressure or application of a vacuum causes the balloons to deflate and the valve **14** to open. Such valves **14** do not require the use of open cell foam cores but may require external devices to monitor drainage lumen parameters and ensure patient safety.

[0056] In another embodiment, the valve or seal **14** is made from a soft rubber or polymer. A central hole, slit or cross in the valve **14** allows for generation of potential space in this normally closed structure. In this embodiment, insertion of a hollow obturator through the valve-enabling adapter **26** and the central hole, slit or cross opens the valve **14**, permitting fluid, air and contaminants to pass through the hollow obturator.

[0057] In yet another embodiment, the valve or seal **14** is a duckbill or one-way valve permitting fluid, air and contaminants to flow from the chest but not permitting introduction of air into the chest. When the trocar **40** or **54** is advanced into the cannula **10**, the valve leaflets are moved into the open position to permit passage. This operation may be performed manually or automatically when trocar **40** or **54** insertion is required. The duckbill valve is typically fabricated from soft polymer materials such as silicone rubber, polyvinyl chloride, polyurethane and the like. The duckbill valve is preferably coated with materials such as heparin or silicone that prevent thrombosis and prevent unwanted permanent sealing of the valve leaflets.

[0058] Figure 5A, Figure 5B, and Figure 5C illustrate another embodiment of the drainage holes **20** at the distal end of the catheter **10**. Figure 5A shows the catheter **10** comprising a knob, lever, or handle **64,** a lock **66,** a control rod **72,** and a sleeve **68**. The sleeve **68** comprises a series of longitudinal slits or slots **60** and a rigid ring **62.** The proximal end of the sleeve **68** is affixed to the catheter **10** and the distal end of the sleeve terminates in the rigid ring **62**

that slides over the catheter **10**. The sleeve is located over the plurality of drainage holes **20** at the distal end of the catheter **10**. The slits or slots **60** are disposed circumferentially around the sleeve **68.** The sleeve **68** is located approximately 20 cm or less from the distal end of the tubing **22** and is preferably located 10cm or less from the distal end of the tubing **22**. The slots **60** are approximately 10cm or less long and preferably 5cm or less long. The slits or slots **60** are approximately 90 degrees apart and are preferably 45 degrees apart. The rigid ring **62** is operably attached to a control rod **72** running through one of the lumens of the multi-lumen tubing **22** and extending to the proximal end of the cannula **10**. As shown in Figure 5C, the control rod **72** is terminated at the proximal end of the cannula **10** with the knob, handle or lever **64** for manual activation. In Figure 5A, the slots **60** are closed.

[0059] Figure 5B shows the distal tip of the cannula **10** when the control rod **72** is retracted and the slots **60** are open. As the control rod **72** is retracted proximally, the distal ring **62** moves proximally, and the slits or slots **60** expand radially and increase their opening size, thus exposing the drainage holes **20** and providing drainage. The control rod **72** may serve an additional purpose of activating the intracorporeal fixation device **18**. The lock **66** at the proximal end of the cannula **10** causes the control rod **72** to maintain its position until reversal is desired. The optional lever **64** provides mechanical advantage and makes it easier to move the control rod **72**.

[0060] In another embodiment, the slots **60** are located in the wall **38** of the multi-lumen tubing **22** and connect the exterior of the catheter **10** with the drainage lumen **32**, replacing the drainage holes **20**. As the control rod **72** is retracted proximally, the slits or slots **60** expand radially and increase their opening size, thus providing drainage.

[0061] In a further embodiment, the cannula **10** of the present invention comprises at least one flexible control rod **72** extending from the distal tip of the cannula **10** to the proximal end of said cannula **10**. The control rods **72** are slideably disposed within one of the lumens of the multi-lumen tubing **22**. The control rods **72** are disposed off-center and terminate at or near the proximal end of the cannula **10** with a handle. The control rods **72** are fabricated from wire, polymer fiber or other flexible material. The cannula **10** further comprises an area of increased flexibility proximal to the distal attachment point of the control rod **72** to the cannula **10**.

[0062] By withdrawing the control rod or rods **72** proximally, the cannula tip may be made to bend in a controlled direction in the area of increased flexibility. Such selective steerability is useful in advancing the cannula **10** through tortuous anatomy.

[0063] The cannula **10** of the present invention is useful during or after many thoracic surgeries and will benefit many patients in the emergency setting. The system is easier to place in the patient than standard chest drainage tubes and may be placed by personnel with less training than physicians (e.g.

paramedics). The system is less likely to be misused than standard chest drainage tubes.

[0064] The cannula **10** of the present invention may be used for abdominal drainage, thoracic drainage, peritoneal dialysis and other procedures. The invention is not limited solely to thoracic procedures but to general mammalian body cavity drainage and/or catheterization.

[0065] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is therefore indicated by the appended claims rather than the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.